

Appln. No. 09/441,140
Amendment dated August 9, 2004
Reply to Office action of June 10, 2004

genetically engineered antibody antigen binding fragment, and a single chain monoclonal antibody, and wherein said anti-aggregation molecule binds to a bioactive native target polypeptide epitope with a high binding constant and is non-inhibitory to the biological activity of the target polypeptide comprising the steps of:

denaturing a target polypeptide which aggregates,
mixing the target polypeptide with said anti-aggregation molecule to form a mixture,
incubating the mixture under conditions allowing for aggregation,
selecting non-aggregated mixtures, and
testing the nonaggregated target polypeptide coupled to the anti-aggregation molecule for bioactivity thereby selecting an anti-aggregation molecule with the chaperone-like activity of anti-aggregation which when coupled to the target polypeptide maintains bioactivity.

2. The method of claim 1 further characterized by the target polypeptide being β -amyloid.

3. A method of selecting an anti-aggregation molecule having the chaperone-like activity of anti-aggregation, wherein the anti-aggregation molecule is selected from the group consisting of a monoclonal antibody, a genetically engineered antibody antigen binding fragment, and a single chain monoclonal antibody, and wherein said anti-aggregation molecule binds to a bioactive native target polypeptide epitope with a high binding constant, reverses

Appln. No. 09/441,140
Amendment dated August 9, 2004
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aggregation and is non-inhibitory to the biological activity of the target polypeptide comprising the steps of:

preparing an aggregated target polypeptide,
mixing the target polypeptide with said anti-aggregation molecule to form a mixture,
selecting mixtures with non-aggregated target polypeptides, and

testing the target polypeptide coupled to the anti-aggregation molecule for bioactivity thereby identifying an anti-aggregation molecule with the chaperone-like activity of anti-aggregation which when coupled to the target polypeptide maintains bioactivity.

4. The method of claim 3 further characterized by the target polypeptide being β -amyloid.

150. A pharmaceutical formulation, comprising:

(A) an antibody or antigen binding fragment thereof,
wherein:

(i) said antibody and said fragment recognize an epitope within residues 1-28 of beta-amyloid, and

(ii) said antibody and said fragment inhibit aggregation of beta-amyloid; and

(B) a pharmaceutically acceptable carrier.

151. The pharmaceutical formulation of claim 150,
wherein said antibody is a monoclonal antibody.

152. The pharmaceutical formulation of claim 151,
wherein said antibody is a human monoclonal antibody.

Appln. No. 09/441,140
Amendment dated August 9, 2004
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153. The pharmaceutical formulation of claim 151, wherein said antibody is a genetically-engineered monoclonal antibody.

154. The pharmaceutical formulation of claim 153, wherein said antibody is a single-chain antibody.

155. The pharmaceutical formulation of any one of claims 150-154, wherein said beta-amyloid is human beta-amyloid.

156. A pharmaceutical formulation, comprising:
(A) an antibody or antigen binding fragment thereof,

wherein:

(i) said antibody is obtainable using residues 1-28 of beta-amyloid as an immunogen, and

(ii) said antibody and said fragment inhibit aggregation of beta-amyloid; and

(B) a pharmaceutically acceptable carrier.

157. The pharmaceutical formulation of claim 156, wherein said antibody is a monoclonal antibody.

158. The pharmaceutical formulation of claim 157, wherein said antibody is a human monoclonal antibody.

159. The pharmaceutical formulation of claim 157, wherein said antibody is a genetically-engineered monoclonal antibody.

Appln. No. 09/441,140
Amendment dated August 9, 2004
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160. The pharmaceutical formulation of claim 159, wherein said antibody is a single-chain antibody.

161. The pharmaceutical formulation of any one of claims 156-160, wherein said beta-amyloid is human beta-amyloid.

162. A pharmaceutical formulation, comprising:

(A) an antibody or antigen binding fragment thereof,

wherein:

(i) said antibody and said fragment recognize an epitope within residues 1-28 of beta-amyloid, and

(ii) said antibody and said fragment maintain the solubility of soluble beta-amyloid; and

(B) a pharmaceutically acceptable carrier.

163. The pharmaceutical formulation of claim 162, wherein said antibody is a monoclonal antibody.

164. The pharmaceutical formulation of claim 163, wherein said antibody is a human monoclonal antibody.

165. The pharmaceutical formulation of claim 163, wherein said antibody is a genetically-engineered monoclonal antibody.

166. The pharmaceutical formulation of claim 165, wherein said antibody is a single-chain antibody.

Appln. No. 09/441,140
Amendment dated August 9, 2004
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167. The pharmaceutical formulation of any one of
claims 162-166, wherein said beta-amyloid is human beta-
amyloid.